K132159

510(k) SUMMARY

CONTACT
Emily Ziegler
Scientist I
Gen-Probe Prodesse, Inc.
20925 Crossroads Circle
Waukesha, WI 53186

AUG 14 2013

PREDICATE DEVICE
K102952, ProAdeno™+ Assay

NAME OF DEVICE

Trade Name:	Prodesse® ProAdeno®+ Assay
Regulation Number:	21 CFR 866.3980
Product Code:	OCC, OOI
Classification Name:	Nucleic acid amplification assay for detection of human adenovirus

INTENDED USE

The Prodesse® ProAdeno®+ Assay is a multiplex Real Time PCR *in vitro* diagnostic test for the qualitative detection of human Adenovirus (HAdV) DNA isolated and purified from nasopharyngeal (NP) swab specimens obtained from individuals exhibiting signs and symptoms of acute respiratory infection. This test is intended for use to aid in the diagnosis of HAdV infections in humans in conjunction with other clinical and laboratory findings. The test detects, but does not differentiate, serotypes 1-51.

Negative results do not preclude HAdV infection and should not be used as the sole basis for treatment or other patient management decisions.

PRODUCT DESCRIPTION

The ProAdeno+ Assay enables detection of human adenovirus and internal control nucleic acid. Nasopharyngeal swab specimens are collected from patients with signs and symptoms of a respiratory infection using a polyester, rayon or nylon tipped swab and placed into viral transport medium.

A Universal Internal Control (UIC) is added to each sample prior to nucleic acid isolation to monitor for inhibitors present in the specimens. The isolation and purification of the nucleic acids is performed using either a MagNA Pure LC Instrument (Roche) and the MagNA Pure Total Nucleic Acid Isolation Kit (Roche) or a NucliSENS® easyMAG™ System (bioMérieux) and the Automated Magnetic Extraction Reagents (bioMérieux).

The purified nucleic acids are added to ProAdeno+ Supermix included in the ProAdeno+ Assay Kit. The ProAdeno+ Supermix contains oligonucleotide primers, target-specific oligonucleotide probes and a Taq DNA polymerase. The primers are complementary to highly conserved regions of the HAdV hexon gene. The probes are dual-labeled with a reporter dye attached to the 5'-end and a quencher dye attached to the 3'-end (see table below).

Analyte	Gene Targeted	Probe Fluorophore	AbsorbancePeak	EmissionPeak	Instrument Channel
Adenovirus	hexon	FAM	495 nm	520 nm	FAM
Universal Internal Control	NA	Quasar 670	647 nm	667 nm	Cy5

Amplification of DNA is performed in a Cepheid SmartCycler® II instrument. In this process, the probe anneals specifically to the template followed by primer extension and amplification. The ProAdeno+ Assay is based on Taqman chemistry, which utilizes the 5' – 3' exonuclease activity of the Taq polymerase to cleave the probe thus separating the reporter dye from the quencher. This generates an increase in fluorescent signal upon excitation from a light source. With each cycle, additional reporter dye molecules are cleaved from their respective probes, further increasing fluorescent signal. The amount of fluorescence at any given cycle is dependent on the amount of amplification products present at that time. Fluorescent intensity is monitored during each PCR cycle by the SmartCycler II instrument.

DEVICE COMPARISON

The modified ProAdeno+ Assay differs from the current kit in the following ways:

- Outsourcing of internal control stock manufacturing leads to changes in the internal control;
- The 1:10 dilution step of the positive control performed by customers has been removed.

The labeling was updated accordingly to incorporate the modifications listed above.

SUBSTANTIAL EQUIVALENCE

1. The Intended Use and Warnings or Precautions of the modified device as described in the labeling have not changed.
2. The modifications detailed in the table below had not had any effect or caused any changes to the fundamental scientific technology of the device.

Modification	Potential Impact of Modification	Verification/Validation Result
Outsourcing of controls leading to minor changes in sequence.	Modification of the internal control may affect the ability of the device to detect the target	The modified UIC did not affect the ability of the ProAdeno+ Assay to detect target organisms at the limit

Modification	Potential Impact of Modification	Verification/Validation Result
	organisms. Additionally, it may change the clinical performance of the ProAdeno+ Assay.	of detection as evinced by the results of Analytical Sensitivity, IC Interference, Extractor Equivalency, and Sample Stability studies. Additionally, the results of a retrospective clinical comparison study demonstrated the modified ProAdeno+ Assay with UIC continues to meet the performance claims for the current ProAdeno+ Assay.
Modified positive controls provided "at use" concentration, no dilution is necessary.	Changes in the testing concentration may affect the performance of the positive control in terms of stability or ability to detect global assay failures.	A Positive Control Effectiveness Study demonstrated the positive control's continued ability to monitor for global assay failures at the increased testing concentration.

3. Verification and validation studies performed demonstrated that all clinical and analytical performance/functionality remains unchanged from the previous device.
4. The appropriate Design Control activities were performed;
    a. A Risk Analysis was performed and did not raise any new concerns of safety and efficacy associated with the modifications.
    b. A declaration of conformity with design controls has been submitted.

The modified ProAdeno+ Assay is substantially equivalent to the current legally marketed device, ProAdeno+ Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 14th, 2013

Emily Ziegler
Scientist I
Gen-Probe Prodesse, Inc.
20925 Crossroads Circle
Waukesha, WI 53186

Re: K132159
Trade/Device Name: Prodesse® ProAdeno®+ Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Virus Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OCC, OOI
Dated: July 11, 2013
Received: July 16, 2013

Dear Ms. Ziegler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K132159
Device Name: Prodesse® ProAdeno®+ Assay

Indications for Use:

The Prodesse® ProAdeno®+ Assay is a multiplex Real Time PCR *in vitro* diagnostic test for the qualitative detection of human Adenovirus (HAdV) DNA isolated and purified from nasopharyngeal (NP) swab specimens obtained from individuals exhibiting signs and symptoms of acute respiratory infection. This test is intended for use to aid in the diagnosis of HAdV infections in humans in conjunction with other clinical and laboratory findings. The test detects, but does not differentiate, serotypes 1-51.

Negative results do not preclude HAdV infection and should not be used as the sole basis for treatment or other patient management decisions.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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